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Designing, Fabrication, and Efficacy Testing of a Surgical Guide for Accurate Positioning of Dental Implants in Completely Edentulous Mandibular Models

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Objectives Ideal implant placement decreases the postoperative surgical, prosthetic, and functional complications. This study aimed to design and fabricate a surgical guide for accurate positioning and angulation of dental implants in edentulous mandibular models and assess its efficacy.

Methods After initial designing and fabrication of resin model of the surgical guide and eliminating its shortcomings, the final model was fabricated using 6061t6 aluminum alloy by a computer numerical control machine. The efficacy of the designed surgical guide was tested by placing 16 implants with the help of the surgical guide in two completely edentulous mandibular models. Next, cone-beam computed tomography DICOM images were obtained from the inserted dental implants, and analyzed by NNT Viewer software. One-sample t-test was applied to compare deviations of implant angle and distance from the planned angulation/position at $P<0.05$ level of significance.

Results The mean angular deviation between the planned and placed implants was 3.31±1.2° and 0.97±0.56° for 0° and 15° implants, respectively. The mean linear deviation between the planned and placed implants was 1.00±0.75 mm. Although the linear and angular differences between the planned and placed implants were statistically significant ($P<0.05$), they were clinically acceptable.

Conclusion The designed surgical guide showed the expected efficacy with maximum mesiodistal angular deviation < 5° and linear deviation < 1 mm in 56% and < 1.5 mm in 75% of the placed implants, compared with the planned angulations/positions.

Keywords Dental Implants; Jaw, Edentulous; Mandible; Surgery, Computer-Assisted

Introduction

A successful implant treatment requires effective osseointegration of implant in an appropriate location along with efficient prosthetic restoration. To achieve this goal, appropriate treatment planning according to the radiographic and clinical examinations of bone morphology, and selection of adequate height and correct angulation of implant are imperative.[1] An appropriate treatment plan should determine the optimal three-dimensional position of implant in the alveolar bone to achieve acceptable function and optimal esthetics of the final restoration, and prevent biomechanical complications and subsequent implant failure.[2] Accurate preoperative assessment of the bone quality and quantity is highly important for prevention of complications and traumatization of important anatomical structures, and enhancement of prosthetic treatment.[3] In general, ideal placement and distribution of dental implants is imperative to ensure optimal mechanical and esthetic results regarding the final restoration, and ensure easy oral hygiene maintenance.[1]

Computer-guided surgery enables implant placement according to the prosthetic treatment plan, and conduction of flapless surgery or with a small incision. It also minimizes the risk of iatrogenic trauma to important anatomical structures, decreases the duration of surgical procedure, increases the predictability of an efficient restoration, and decreases adverse psychological and ergonomic consequences.[4] However, deviation from the planned position/angulation is the most important concern in computer-guided surgery. Thus, it is imperative to clinically assess the accuracy and efficacy of the surgical guides prior to conduction of surgical procedures.[5]

Surgical guides are mechanical elements used as an adjunct to enhance the surgical process of implant placement. Their main advantages include availability and cost-effectiveness.

A paralleling guide block is a novel surgical tool fabricated to enhance parallel and symmetrical placement of dental implants. However, to the best of the authors' knowledge, only one report published in 2015 is available regarding its efficacy.[6] Fauroux et al,[7] in 2018 evaluated the efficacy of a novel surgical system for dental implant surgery by installing 67 implants. However, their study lacked statistical analysis of the data to assess the accuracy and efficacy of the suggested system. Dental drill guide apparatus and Abrahami drill guide kit are commercially available in the market. However, search of the literature yielded no documentation regarding their efficacy. Surgical guides are introduced to the market for more accurate implant placement with more predictable results. In order to have an efficient, easily available, and cost-effective surgical guide, this study aimed to design and fabricate a new surgical guide for more accurate implant positioning and angulation in completely edentulous mandibles and assess its efficacy.

Methods and Materials

A technological study was carried out at the Periodontics Department of School of Dentistry, Shahid Beheshti University of Medical Sciences to design and fabricate a surgical guide for accurate dental implant placement. Experimental tests were also performed to assess its efficacy by analyzing the angular and linear deviations between the planned and placed implants with the help of the surgical guide. This surgical guide was primarily designed aiming to improve the accuracy of implant placement in terms of symmetry and parallelism and to decrease perioperative errors and their adverse biomechanical effects on the final restoration. The surgical guide was three-dimensionally designed by SolidWorks 2019 software program. A resin pattern of the primary design was then fabricated and evaluated. After eliminating the primary shortcomings and finalizing the design, the final product was fabricated using 6061t6 aluminum alloy by a computer numerical control machine. The fabricated surgical guide includes three main components namely the main body, working cylinder, and centralizer (Figure 1).

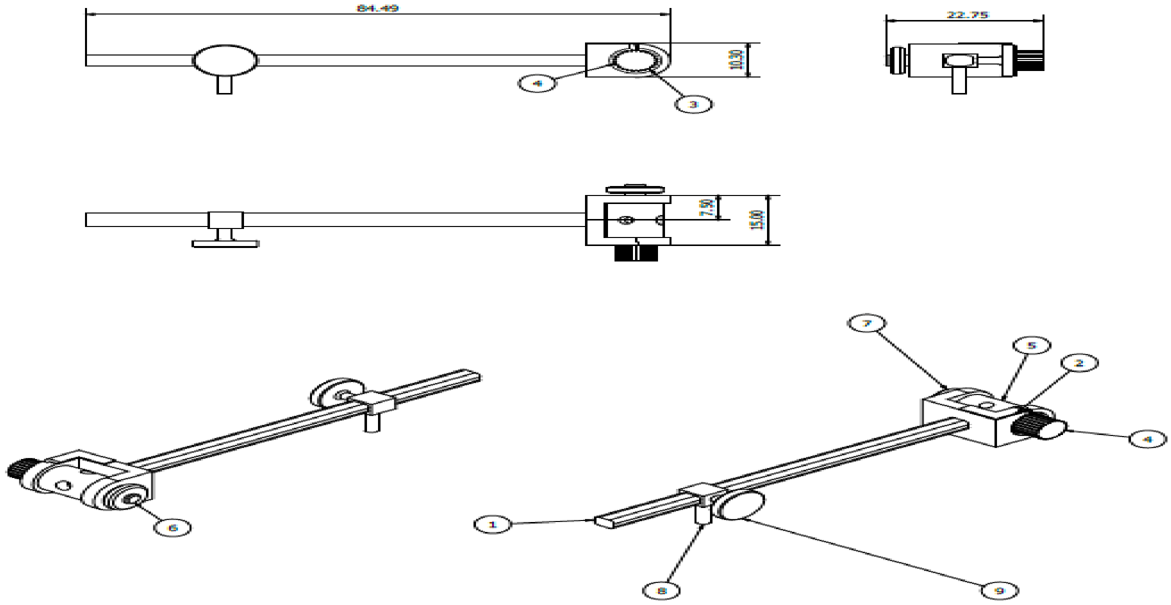

Figure 1: Perspective view of the mechanics of the designed surgical guide: (1) main body; (2) angle lock; (3) gear; (4) angle regulator screw; (5) working cylinder; (6) M3 screw; (7) screw fixer; (8) centralizer; (9) locking screw

Prior to implant placement with the help of the designed surgical guide, the midline of an edentulous jaw model was marked at equal distances from the coronoid processes of the edentulous model. A hole with 8 mm depth and 2 mm diameter was created at the midline. Next, the centralizer pin was placed in the hole and by moving the graded arm within the centralizer, the adjustments for a proper surgical site for implant placement were performed. The entire device can rotate around the centralizer pin to be transferred to the other quadrant of the jaw without requiring re-installation.

Two holes, perpendicular to each other, are located on the lateral surface of the working cylinder in line with the diameter of the cylinder. The holes have 2.3 mm and 2.9 mm diameters (including 0.1 mm free distance between the drill and the guiding pin), which correspond to the diameters of the first two surgical drills used for implant hole preparation, to create a guiding path. The optimal angulation of the drilling path is adjusted in the working cylinder. In order to create the next path corresponding to the diameter of the next drill, the angulation should be changed by 90°. After finalizing the adjustments, drilling is possible through the guiding path. Presence of two different sizes of guiding paths for the drill without requiring component replacement enhances the surgical procedure (Figure 2).

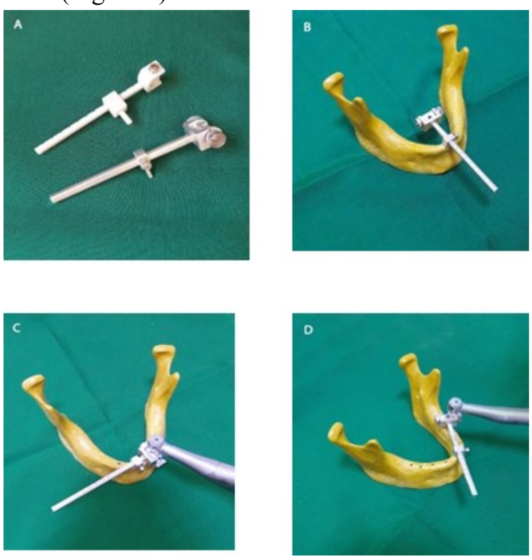

Figure 2: (A) Resin pattern and aluminum model of the designed surgical guide; (B) placement of centralizer pin at the midline of the edentulous mandibular model; (C) drilling through the adjusted guiding path at 10 mm distance from the midline; (D) drilling through the adjusted guiding path at 35 mm distance from the midline

Next, 16 implants (SIC Max implants, ø 3.4 × 9.5 mm, SIC Invent, Switzerland) were placed in two completely edentulous models of the mandible (simulating the anatomy of a mature jawbone) to assess the efficacy of the designed surgical guide.

The sample size was calculated by using the sample size calculation formula for one-sample analytical studies. Accordingly, the required sample size was calculated to be 4 for measurement of angular deviations, and 15 for measurement of linear deviations.

n=■(〖[Z_(1-α/2) ┤+├ Z_(1-β)]〗^2&× 〖(S)〗^2)/(μ-μ_0)^2

In this formula, S indicates the standard deviation of the variable obtained from primary piloting of the data (1.2), and (μ-μ_0) is the mean difference between the planned and placed implants.

After installation and adjustment of the surgical guide, drilling (at a speed of 1200 min-1) was performed at the desired distances (10, 20, 30, and 35 mm from the midline at both sides) according to the protocol of the manufacturer by a senior dental student with no prior experience in surgical implant placement and no prior practice regarding the use of the designed surgical guide. The implants were placed with 25 N/cm torque. Eight implants were placed perpendicular to the bone surface with 0° angular deviation relative to the vertical index at the midline. In the second edentulous model of the jaw, drilling was performed at the desired distances from the midline for placement of 8 implants with 15° angulation relative to the vertical index at the midline, and the implants were subsequently placed. Prior to obtaining cone-beam computed tomography DICOM images, an aluminum sheet with 2 mm thickness, 2 mm diameter, and 10 mm length was placed at the location of vertical index at the midline, and then cone-beam computed tomography DICOM images were obtained by New Tom VGI scanner (QR, Verona, Italy) with the exposure settings of 159 µm minimum voxel size, 3.3-10 mA, 110 kVp, and 12 x 8 cm field of view in high resolution mode.

Statistical analysis:

The angular deviation of the longitudinal axis of the placed implants relative to the vertical index at the midline, and also the distance between the placed implants and the midline were measured by using NNT Viewer software (NewTom CGI, Verona, Italy). Data were analyzed by SPSS version 21 (SPSS Inc., IL, USA). One-sample t-test was applied to compare the variables at P<0.05 level of significance.

Results

After statistical analysis of the data obtained from 16 DICOM images of implants placed in two edentulous models of the mandible, the mean angular deviation between the planned and placed implants was separately calculated for 0° and 15° implants. Table 1 shows the mean angular deviation between the planned and placed implants (with the help of surgical guide) in mesiodistal direction.

Table 1- Mean angular deviation between the planned and placed implants (with the help of surgical guide) in mesiodistal direction

Variable	Number	Angular deviation in mesiodistal direction	Standard deviation	P value
Mean angular deviation between the planned and placed implants with 0° angulation	8	3.31	1.20	<0.001
Mean angular deviation between the planned and placed implants with 15° angulation	8	0.97	0.56	<0.002

Although comparison of the mean angular deviation between the planned and placed implants with 0° and 15° angulations by one-sample t-test revealed statistically significant differences (P<0.001, and P<0.002, respectively), these differences were clinically acceptable. Table 2 presents the mean linear deviation (relative to the midline index) between the planned and placed implants.

Table 2- Mean linear deviation between the planned and placed implants (with the help of surgical guide) at 10, 20, 30 and 35 mm distances from the midline

Variable	Number	Linear deviation relative to the midline	Standard deviation	P value
Mean linear deviation between the planned and placed implants	16	1.00	0.75	<0.001

Comparison of the mean linear deviation between the planned and placed implants (relative to the midline) by one-sample t-test revealed statistically significant differences (P<0.001). However, in general, the mean linear deviations between the planned and placed implants at 10, 20, 30 and 35 mm distances from the midline (in mesiodistal direction) were clinically acceptable

Discussion

At present, dental implants are increasingly used for replacement of the lost teeth. Thus, aside from adequate knowledge, precise, efficient, easily available, and cost-effective tools are required for implant placement in ideal position. Considering the significance of accurate implant placement in terms of symmetry and parallelism, this study aimed to design and fabricate a surgical guide for accurate positioning and mesiodistal angulation of implants according to the clinical conditions during surgery in completely edentulous ridges. The efficacy of the designed surgical guide

was also evaluated.
The results showed that the mean angular deviation between the planned and placed implants was 3.31±1.2° and 0.97±0.56° for 0° and 15° implants, respectively. These values were within the range of deviations reported by an in vitro study on the accuracy of implant placement using a surgical guide template by an inexperienced clinician in a unilaterally edentulous mandible. They reported the maximum mean angular deviation of 5.46±2.09°, compared with the planned angulation for the implant placed at the site of tooth #7.[8] Another in vitro study conducted in 2019 reported a mean angular deviation of 1.6±1.3° in dynamic computer-guided placement of dental implants.[9] An in vivo study in 2008 used stereolithographic surgical guides and reported a mean angular deviation of 4.9±2.36°.[10] A review study carried out in 2018 evaluated the accuracy of dental implant placement with the help of a static computerized surgical guide and reported the maximum mean angular deviation of 8.4±4.20°, and minimum mean angular deviation of 1.85±0.75° from the planned values.[11] A static 3D finite element analysis of the effect of implant inclination (0°, 17°, 30°, and 45°) on stress distribution in mandibular cortical bone and dental implants indicated improved stress distribution in 30° or 45° posterior inclination of implants and use of shorter cantilevers.[12] Another study compared the magnitude and pattern of stress distribution in the maxilla around dental implants by using different numbers and angulations of implants. Four implants were placed with 0°, 15°, 30° and 45° distal angulations. The results showed that increasing the angulation of posterior implants decreased the length of cantilever and led to subsequent reduction in stress level in cancellous and cortical bones.[13] Considering the abovementioned two studies, the ability to change the angulation by the surgical guide designed in this study can be considered as a favorable feature of this device.
In the present study, the mean linear deviation between the planned and placed implants was 1.00±0.75 mm. An in vitro study on the accuracy of implant placement by an inexperienced clinician using a surgical guide template reported that the maximum mean distal deviation was 0.6±0.15 mm in implant base, and 1.14±0.33 mm at the apex.[8] Also, another in vitro study conducted in 2019 reported a mean linear deviation of 0.85±0.41 mm two-dimensionally, and 1.29±0.46 mm three-dimensionally in use of a dynamic surgical guide.[9] An in vivo study reported a mean linear deviation of 1.22±0.85 mm at the cervical and 1.5±1 mm at the apex of dental implants.[10] Moreover, a review study conducted in 2018 assessed the accuracy of static guides, and reported a maximum mean deviation of 2.17±0.87 mm at the cervical and 2.86±2.17 mm at the apical region.[11]
The mean linear and angular deviations obtained in our study indicated optimal linear and angular accuracy of implants placed with the help of the designed surgical guide. Although maximum angular deviation in placement of implants with 0° angulation was 4.8° and the maximum linear deviation was 2.4 mm, standard deviation values indicated optimal dispersion of data within the range of mean deviations. It appears that the possible reason for this difference can be initiation of implant placement with 0° angulation with no prior training or expertise of the clinician in using the designed surgical guide; because, in the second series of placed implants, the maximum angular deviation for 15° implants placed with the surgical guide was 1.5° while the minimum deviation was 0.1°. Moreover, manual mechanical adjustment of the surgical guide may be another reason for relatively high error rate in ideal placement of implants, which highlights the need for some modifications in the device. Furthermore, this device allows the use of 2.2 mm and 2.8 mm drills to create the drilling path, and enables manual placement of subsequent drills. Thus, this surgical guide is compatible with different drilling kits. However, the possibility of deviation from the path created by a sequence of drills with a diameter larger than 2.8 mm still exists.
In general, the main goal behind the designing and fabrication of this surgical guide was to introduce an efficient, easily available, and cost-effective guide to enhance implant placement with the desired symmetry and parallelism. Other advantages of this surgical guide include not requiring elevation of an extensive flap, optimal adaptation to the surgical site, the ability to determine the distance between the drilling site and midline of the jaw, easy re-adjustment and transfer of the same distance to the other quadrant of the edentulous jaw around the central pin, the possibility of adjusting the desired implant angulation, having two different diameters of guiding pins corresponding to the diameters of the primary surgical drills without requiring replacement (by only 90° rotation around the horizontal axis of the device for simplified application and reduction of surgical time), small size, and easy use since it does not interfere with the field of view and access of surgeon to the surgical site.

Limitations:

Manual adjustment can serve as a confounding factor, decreasing the accuracy of this surgical guide. However, this problem can be eliminated by further modifications and advancement of this tool to be more practical even in severely atrophic ridges. In addition, to minimize errors, a solution should be found to support all drill sequences with sizes larger than 2 and 2.8 mm. Also improved fixation in the vertical dimension should be considered. For routine use of this surgical guide, radiographic markers should be used to find the best implant insertion site in terms of the available bone volume, adjacent anatomical landmarks, and clinical conditions.
This study had an in vitro design. Further complementary studies are required to eliminate the clinical confounding factors that can affect the results. Until then, the results cannot be generalized to the clinical setting.

Suggestions:

Since this study was performed on edentulous models of the mandible out of a phantom head and without simulation of oral environment, future in vitro studies on the efficacy of this surgical guide are required to simulate the oral clinical conditions. Also, the effect of experience of surgeon on the accuracy of implant placement and surgical time in use of this device should be evaluated in future studies. Comparison of the accuracy of implant placement with the help of this surgical guide and the conventional manual technique can provide valuable information as well. Comparison of the efficacy of this surgical guide with the commercially available tools for this purpose indicates that our designed surgical guide may be suitable for use in the clinical setting. Thus, future studies should focus on modifying and further advancing this tool for application in the clinical setting.

Clinical implications:

Considering the calculated angular and linear deviations that were within the range reported in the literature, it appears that by increasing the accuracy of this surgical guide and acquiring expertise in using it, it can be introduced as an efficient, easily available, and cost-effective tool for ideal implant placement.

Conclusion

The designed surgical guide showed the expected efficacy with maximum mesiodistal angular deviation < 5° and linear deviation < 1 mm in 56% and < 1.5 mm in 75% of the placed implants, compared with the planned angulations/positions.

Conflict of Interest

No Conflict of Interest Declared ■

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